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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,644	03/27/2002	David M. Hodgson	PT-1086 USN	3201
27904	7590	04/01/2004	EXAMINER	
INCYTE CORPORATION 3160 PORTER DRIVE PALO ALTO, CA 94304			STEADMAN, DAVID J	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 04/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/089,644	<b>Applicant(s)</b> HODGSON ET AL.	
	<b>Examiner</b> David J Steadman	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-20 is/are pending in the application.
- 4a) Of the above claim(s) 6-8, 12-15 and 17-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 9, 10, 16 and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>sequence alignment</u> .               |

## **DETAILED ACTION**

### ***Status of the Application***

- [1] Claims 1-10 and 12-20 are pending in the application.
- [2] Applicants' amendment to the claims, filed February 09, 2004, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.
- [3] Applicants' amendment to the specification, filed February 09, 2004, is acknowledged.

### ***Lack of Unity***

- [4] Applicants' election with traverse of the invention of Group XXIII, claims 1-5, 9-10, 16, and 20 filed February 09, 2004, is acknowledged. Applicants assert the unity of invention standard must be applied in national stage applications. Applicants cite MPEP §§ 1800 and 1850 in support of their assertion. In response to applicant's statements, it is noted that the unity of invention standard was applied to original claims 1-19 in evaluating the claims for unity of invention and restriction practice according to 35 U.S.C. 121 and 372. MPEP § 1893.03(d) states, "If the examiner finds that a national stage application lacks unity of invention under § 1.475, the examiner may in an Office action require the applicant in the response to that action to elect the invention to which the claims shall be restricted". Also, according to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. As stated in the Office action mailed January 05, 2004, the inventions of original claims 1-19 do not relate to a single general inventive concept for the reasons

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set forth therein. As such, in accordance with MPEP § 1893.03(d), the examiner properly applied the unity of invention standard to original claims 1-19 in the instant application.

Applicants argue that in view of Example 17, Part 2 of Annex B to the Administrative Instructions Under the PCT, the examiner should withdraw the lack of unity requirement with respect to the polynucleotide and polypeptide claims (claims 1-5, 9-10, 13, and 16) and examine those claims in a single application. Applicant argues the claimed polypeptides and encoding polynucleotides are corresponding technical features, which are common to all pending claims, which serve to technically interrelate all pending claims, and which define the contribution over the prior art. Applicant argues the pending claims are linked to form a single general inventive concept, and applicant is therefore entitled to prosecute all pending claims in a single application. Applicants' argument is not found persuasive.

According to PCT Rule 13.2, unity of invention exists only when there is a shared same or corresponding special technical feature among the claimed inventions. The special technical feature of Group XXIII is a polynucleotide, which encompasses polynucleotides that do not correspond to the polypeptide of claim 13. See particularly the polynucleotides of claim 1 part b) and claim 3. Therefore, the polynucleotide of Group XXIII does not share a corresponding special technical feature with the polypeptide of claim 13, and consequently, these inventions do not have unity of invention.

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[5] Applicants' request for rejoinder of claims 6-8, 12, 15, and 17-20 as allegedly being drawn to methods of using the polynucleotide of elected Group XXIII is acknowledged. Regarding claim 20, to the extent the claim recites a method that is not patentably distinct from the method of claim 5 (claim 20 appears to be an exact duplicate of claim 5), claim 20 is being examined on the merits. Regarding the claims 6-8, 12, 15, and 17-19, it is noted that where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. As the claims of Group XXIII are not yet allowable for the reasons stated below, rejoinder is not yet required. If the polynucleotide of Group XXIII is found to be allowable, withdrawn claims will then be evaluated for rejoinder according to MPEP § 821.04.

[6] The requirement is still deemed proper and is therefore made FINAL.

[7] Claims 6-8, 12-15, and 17-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim.

[8] Claims 1-5, 9-10, 16, and 20 are being examined on the merits.

***Priority***

[9] Applicants' claim to domestic priority under 35 USC 119(e) to provisional applications 60/156,565, filed 09/28/1999, and 60/168,197, filed 11/30/1999, is acknowledged. It is noted that the specification has been amended (see the amendment filed February 09, 2004) such that the instant application claims priority to those applications cited above. It should be further noted that SEQ ID NO:23 of the instant application appears to be identical to nucleotides 20-3946 of SEQ ID NO:96 of provisional application 60/156,565 and also appears to be identical to SEQ ID NO:160 of provisional application 60/168,197.

#### ***Specification/Informalities***

[10] The attempt to incorporate subject matter into this application by reference to a hyperlink embedded in the specification (e.g., page 43, line 10) is improper. Incorporation of subject matter into the patent application by reference to a hyperlink and/or other forms of browser-executable code is considered to be an improper incorporation by reference. See MPEP 608.01 regarding hyperlinks in the specification and 608.01(p), paragraph I regarding incorporation by reference.

#### ***Claim Objections***

[11] Claim 1 is objected to because of the following informalities: the term "a a polynucleotide" in claim 1 part a) is grammatically incorrect and should be replaced with, for example, "a polynucleotide". Appropriate correction is required.

[12] Claim 1 is objected to in the recitation of "SEQ ID:23" and should be replaced with "SEQ ID NO:23" in accordance with 37 CFR 1.821(d).

[13] Claim 20 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 5. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

***Claim Rejections - 35 USC § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

[14] Claim(s) 1-5, 9-10, 16, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 (claims 2-5, 9-10, 16, and 20 dependent therefrom) is indefinite in the recitation of "complementary". The specification defines the term "complementary" as, "'partial' such that only some of the nucleotides bind" or "'complete' such that total complementarity exists between the single stranded molecules" (page 8, top of the specification). As such, it is unclear as to whether the complementary polynucleotides are partial or complete complements. In the interest of advancing prosecution, the term "complementary" has been interpreted as completely complementary. If the examiner's

interpretation of the term is incorrect, applicant should so state and clarify the record. It is suggested that applicant clarify the meaning of the term "complementary" as being either a partial or complete complement.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

**[15]** Claims 1-5, 9-10, 16, and 20 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or well-established utility. The specification asserts the polynucleotide of SEQ ID NO:23 has use "in the diagnosis, study, prevention, and treatment of diseases associated with, as well as effects of exogenous compounds on, the expression of molecules for disease detection and treatment" (page 1, lines 7-10 and page 18, lines 27-34 of the instant specification). However, these asserted utilities are not substantial as further research is required to identify a "real world" use for the claimed polynucleotide due to the failure of the specification to provide the necessary guidance for using the claimed polynucleotide for diagnosis, prevention, and treatment of diseases associated with, as well as effects of exogenous compounds on, the expression of molecules for disease detection and treatment. The specification fails to provide any guidance regarding those specific diseases that can be diagnosed, prevented, or treated and/or guidance for diagnosing, preventing, or treating a specific disease. Instead, the specification merely provides a



vast number of diseases and disorders (see page 22) without providing specific guidance regarding a disease or diseases that can be diagnosed, prevented, or treated or without providing specific guidance as to how one would specifically treat such a disease, e.g., route of administration, dosage, toxicity, etc. Furthermore, the specification fails to provide guidance for interpreting the results of an expression analysis of SEQ ID NO:23 due to exogenous compounds and what the results would mean. In this case, the asserted utility is to measure the expression of a polynucleotide that has no specific and substantial utility, which is not a substantial utility according to MPEP 2107.01. Contrast this with Shattuck-Eidens et al. (US Patent 5,693,473) who teach mutant alleles of the *BRCA1* gene that predispose a patient to developing breast and ovarian cancers (abstract) and provide guidance in the specification for using the mutant alleles to determine a patient's predisposition to developing breast and ovarian cancers. In this case, further experimentation is required to use the claimed polynucleotide for diagnosis, prevention, and treatment of diseases associated with, as well as to determine the effects of exogenous compounds on, the expression of molecules for disease detection and treatment. Consequently, the asserted utilities are not substantial. See *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966). The specification must teach a skilled artisan how to use what is claimed and not merely provide a blueprint for further experimentation in order for an artisan to identify a use for the claimed invention. As stated in *Brenner v. Manson*, 383 U.S. 519 535-536, 148 USPQ 689, 696 (1966), "[a] patent is not a hunting license. It is not a reward for the

search, but compensation for its successful conclusion". Here the specification fails to provide a specific benefit in currently available form for the claimed polynucleotide.

***Claim Rejections - 35 USC § 112, First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**[16]** Claims 1, 3-5, 9-10, 16, and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 (claims 4-5, 9-10, 16, and 20 dependent therefrom) and 3 are drawn to (in relevant part) a genus of polynucleotides comprising a naturally occurring polynucleotide at least 90% identical to SEQ ID NO:3 (claim 1) or a polynucleotide comprising at least 60 contiguous nucleotides thereof. For claims drawn to a genus, MPEP § 2163 states the written description requirement for a genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and

structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406. MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. In this case, the specification discloses only a single representative species of the recited genus of polynucleotides, i.e., SEQ ID NO:23. The genus of claimed polynucleotides encompasses species that are WIDELY variant in their structures and functions. As such, the disclosure of the single representative species is insufficient to be representative of the attributes and features of all species encompassed by the claimed genus. Given the lack of description of a representative number of polynucleotides, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicant was in possession of the claimed invention. Furthermore, it is noted that the genus of polynucleotides of claim 1 part b) is limited to those that are "naturally occurring". The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997), quoting *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Also, MPEP § 2163

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states (citing *Amgen*, 927 F.2d at 1206, 18 USPQ2d at 1021), "A gene is a chemical compound, albeit a complex one, and it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials". In this case, the specification fails to provide those characteristics that distinguish the subgenus of "naturally occurring" polynucleotides within the identity limitation of the claim from the larger genus of polynucleotides that includes both "naturally occurring" and non-naturally occurring polynucleotides. For the reasons stated above, the specification fails to provide adequate written description for the recited genus of polynucleotides.

**[17]** Claims 1-5, 9-10, 16, and 20 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial or specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

**[18]** Even if applicant demonstrates the polynucleotide of SEQ ID NO:23 has a specific and substantial or well-established utility, the following rejection still applies. Claim(s) 1, 3-5, 9-10, 16, and 20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polynucleotide of SEQ ID NO:23, does not reasonably provide enablement for the broad scope of claimed polynucleotides, including *all* polynucleotides comprising a naturally occurring polynucleotide that is at least 90% identical to SEQ ID NO:23 and complements and RNA equivalents thereof and *all* polynucleotides comprising at least 60 contiguous nucleotides thereof.

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It is the examiner's position that undue experimentation would be required for a skilled artisan to make and/or use the entire scope of the claimed invention. Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)) as follows: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. See MPEP § 2164.01(a). The Factors most relevant to the instant rejection are addressed in detail below.

- The claims are overly broad in scope: The claims are so broad as to encompass *all* polynucleotides comprising a naturally occurring polynucleotide that is at least 90% identical to SEQ ID NO:23 and complements and RNA equivalents thereof and *all* polynucleotides comprising at least 60 contiguous nucleotides thereof. The broad scope of claimed polynucleotides is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polynucleotides broadly encompassed by the claims. In this case the disclosure is limited to the polynucleotide of SEQ ID NO:23.
- The lack of guidance and working examples: The specification provides only a single working example of the claimed polynucleotide, i.e., SEQ ID NO:23. This single working example fails to provide the necessary guidance for making and/or using the

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entire scope of polynucleotides. The specification fails to provide guidance regarding those nucleotides of SEQ ID NO:23 that may be altered by substitution, addition, insertion, and/or deletion with an expectation of maintaining the desired activity.

Furthermore, the specification fails to provide guidance as to how to use those variant nucleic acids – both naturally and non-naturally occurring - that encode polypeptides having activities other than the desired activity, e.g., nucleic acids encoding non-functional polypeptides or polypeptides having activity other than the polypeptide encoded by SEQ ID NO:23.

- The high level of unpredictability in the art: The nucleotide sequence of an encoding nucleic acid determines the corresponding encoded protein's structural and functional properties. Predictability of which changes can be tolerated in an encoded protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e., expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. The positions within an encoding nucleic acid's sequence where modifications can be made with a reasonable expectation of success in obtaining an encoded polypeptide having the desired activity/utility are limited in any protein and the result of such modifications is highly unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g., multiple substitutions. In this case, the necessary guidance has not been provided in the specification as explained in detail

above. Thus, a skilled artisan would recognize the high degree of unpredictability that the entire scope of polynucleotides would encode a polypeptide having the desired activity.

- The state of the prior art supports the high level of unpredictability: The state of the art provides evidence for the high level of unpredictability in altering a polynucleotide sequence with an expectation that the encoded polypeptide will maintain the desired activity/utility. For example, Branden et al. ("Introduction to Protein Structure", Garland Publishing Inc., New York, 1991) teach "[p]rotein engineers frequently have been surprised by the range of effects caused by single mutations that they hoped would change only one specific and simple property in enzymes" and "[t]he often surprising results of such experiments reveal how little we know about the rules of protein stability... ..they also serve to emphasize how difficult it is to design *de novo* stable proteins with specific functions" (page 247). While it is acknowledged that this reference was published in 1991, to date there remains no certain method for reasonably predicting the effects of even a *single* amino acid mutation on a protein. Thus, the prior art acknowledges the unpredictability of altering a protein-encoding sequence with an expectation of obtaining a protein having a desired function and discloses that even a single substitution in a polypeptide's amino acid sequence may completely alter the function of a polypeptide. Furthermore, it is known in the art that two naturally occurring nucleic acids that are highly related with respect to nucleic acid sequence identity can have different functions. For example, Seffernick et al. (J Bacteriol 183:2405-2410)

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teach two nucleic acids that share 99% sequence identity, but encode polypeptides having distinct functions.

- The amount of experimentation required is undue: While methods of generating variants of a given polynucleotide, e.g., by mutagenesis, and methods of isolating homologous polynucleotides, e.g., by hybridization, are known, it is not routine in the art to screen for *all* polynucleotides having a substantial number of substitutions or modifications and encoding polypeptides having *any* function, as encompassed by the instant claims. Thus, in view of the overly broad scope of the claims, the lack of guidance and working examples provided in the specification, and the high degree of unpredictability as evidenced by the prior art, undue experimentation would be necessary for a skilled artisan to make and use the entire scope of the claimed invention.

As such, applicant has not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).



The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**[19]** Claim(s) 3 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Ni et al. (US Patent Application Publication 2003/0050460 A1). Claim 3 is drawn to an isolated polynucleotide comprising at least 60 contiguous nucleotides of a polynucleotide of claim 1. Claim 16 is drawn to a microarray comprising the polynucleotide of claim 3. Ni et al. teach an isolated polynucleotide having a nucleotide sequence having at least 60 contiguous nucleotides of SEQ ID NO:23 (see attached sequence alignment) and teach their nucleic acid as part of a gene chip (page 55, left column). This anticipates claims 3 and 16 as written.

### ***Conclusion***

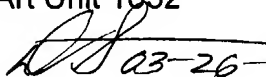
**[20]** Status of the claims:

- Claims 1-10 and 12-20 are pending.
- Claims 6-8, 12-15, and 17-19 are withdrawn from consideration.
- Claims 1-5, 9-10, 16, and 20 are rejected.
- No claim is in condition for allowance.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (571) 272-0942. The Examiner can normally be reached Monday-Friday from 7:00 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The FAX number for submission of official papers to Group 1600 is (703) 872-9306. Draft or informal FAX communications should be directed to (571) 273-0942. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.  
Patent Examiner  
Art Unit 1652

 03-26-04